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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,291	OKO ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *1-7,16-47,49-52,54-59,63,64 and 69-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15,48,53,60-62 and 65-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5/9/02*.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Priority Documents

1. The instant application claims the foreign priority of Canada Application 2307128, filed May 25, 2000. However, the priority document does not appear to have been provided. A copy of the Canadian document should be provided to perfect the priority.

Election/Restrictions

2. Applicant's election with traverse of Group II, claims 8-15, 48, 53 and 60-62, and SEQ ID NO:4, in the Response filed November 14, 2003 is acknowledged. The traversal is on the ground(s) that many Groups have the same classification (e.g., Groups I, V-X, XII, XIV and XV are classified in class 530, subclass 350, and class 514, subclass 2), thus, Examiner's contention that the inventions have acquired a separate status in the art as shown by their different classification is unclear; SEQ ID NO:4 and SEQ ID NO:11 are variant sequences obtained from different species, and are functionally similar as being involved in spermatozoa development; and claims 42 and 43 are claims reciting a gene encoding PT32 and the search for this subject matter will be no more extensive than the search required for claim 14, thus applicant requests reconsideration of the restriction requirement. Regarding SEQ ID NOs: 4 and 11, the argument is persuasive, thus, both sequences are examined. Regarding claims 42 and 43, the argument is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that there is no additional search needed. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, coexamination of claims 42 and 43 would require additional search of class 800, subclass 8. Therefore, coexamination of each of these inventions

would require a serious additional burden of search. Regarding different groups having the same classification, the restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

In the preliminary amendment filed November 14, 2003, claims 6, 8-10, 47, 48, 53, 54 and 56-58 have been amended, and new claims 65-72 have been added. Among the new claims, claims 65-58, directed to polynucleotides, belong to Group II, while claims 69-72, directed to a method for enhancing fertility in a mammal comprising expressing the polynucleotide, belong to Group VII. Therefore, claims 8-15, 48, 53, 60-62 and 65-68, and SEQ ID NOs:4 and 11, and polynucleotides encoding a polypeptide comprising SEQ ID NOs:5 and 12 are examined.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-15, 48, 53, 60-62 and 65-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a specific polynucleotide sequence such as

SEQ ID NO:4 or 11, or a polynucleotide encoding a polypeptide comprising the sequence of SEQ ID NO:5 or SEQ ID NO:12; a gene or a vector comprising the polynucleotide; a host cell comprising the vector; or a method of producing the polypeptide, does not reasonably provide enablement for a polynucleotide encoding a polypeptide, where the polypeptide comprises at least one of PPPGY and LPPAY, and at least three domains having the sequence of YGXPPXG, or, the polypeptide comprises the sequence of PPXY, and at least three domains having the sequence of YGXPPXG; a gene or a vector comprising the polynucleotide; a host cell comprising the vector; or a method of producing the polypeptide, where the sequence of the polynucleotide encoding the polypeptide is not defined. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 8-15, 48, 53, 60-62 and 65-68 are directed to a polynucleotide encoding a polypeptide, where the polypeptide comprises at least one of PPPGY and LPPAY, and at least three domains having the sequence of YGXPPXG (claims 8-10, 48, 60-62 and 65-68), or, the polypeptide comprises the sequence of PPXY, and at least three domains having the sequence of YGXPPXG (claim 53); a gene (claim 11) or a vector (claims 12 and 13) comprising the polynucleotide; a host cell (claim 14) comprising the vector; or a method of producing the polypeptide (claim 15). The specification, however, only discloses cursory conclusions (pages 4-10) without data supporting the findings, which state that the present invention features perinuclear theca polypeptide comprises at least one of PPPGY and LPPAY, and at least three domains having the sequence of YGXPPXG, or, the polypeptide comprises the sequence of PPXY, and at least three domains having the sequence of YGXPPXG, these polypeptides include

bovine or human PT32 or biologically active fragment thereof; and the polynucleotide encoding the polypeptide. There are no indicia that the present application enables the full scope in view of the polynucleotides encoding the polypeptide which comprises at least one of PPPGY and LPPAY, and at least three domains having the sequence of YGXPPXG, or, the polypeptide comprises the sequence of PPXY, and at least three domains having the sequence of YGXPPXG as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the presence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breadth of the claims:

The breadth of the claims is broad and encompasses unspecified variants regarding the polynucleotides encoding the polypeptides which are variants or fragments of SEQ ID NO: 5 or 12, which are not adequately described or demonstrated in the specification.

(2). The presence or absence of working examples:

The specification indicates the cDNA sequence of PT32 has been identified, the rPT32 has been produced, and the injection of rPT32 into cytoplasm of bovine oocytes yield rates of oocyte activation that were similar to the rate of activation injected with perinuclear theca extracts (Table 1, pages 64-78). However, there are no other working examples indicating the claimed variants except for the polynucleotide sequence of SEQ ID NO:4 or 11.

(3). The state of the prior art and relative skill of those in the art:

The related art (references shown at pages 1-4 of the specification) indicates the perinuclear theca (PT), a cytoskeletal coat of the mammalian sperm nucleus, harbors the oocyte activating factors and provides a mechanism for the release of oscillogens from the sperm head into oocyte cytoplasm at fertilization. However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on identities of polynucleotides which are variants or fragments of SEQ ID NO:4 or 11, or polynucleotides encoding the variants or fragments of SEQ ID NO:5 or 12 to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass many polynucleotides which encode variants or fragments of SEQ ID NO:5 or 12, but the effects of variants and fragments of SEQ ID NO:5 or 12 in inducing oocyte activation are not demonstrated in the specification, the invention is unpredictable regarding the effects of these variants and fragments.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a polynucleotide encoding a polypeptide, where the polypeptide comprises at least one of PPPGY and LPPAY, and at least three domains having the sequence of YGXPPXG, or, the polypeptide comprises the sequence of PPXY, and at least three domains having the sequence of YGXPPXG. The specification indicates the cDNA sequence of PT32 has been identified, the rPT32 has been produced, and the injection of rPT32 into cytoplasm of bovine oocytes yield rates of oocyte activation that were similar to the rate of

activation injected with perinuclear theca extracts (Table 1, pages 64-78). However, there are no other working examples indicating the claimed variants except for the polynucleotide sequence of SEQ ID NO:4 or 11. Furthermore, the specification has not identified any polynucleotide which encodes variants or fragments of SEQ ID NO:5 or 12, nor has demonstrated the effects of variants and fragments of SEQ ID NO:5 or 12 in inducing oocyte activation. Since the specification does not provide sufficient teachings in the polynucleotide sequence encoding the variants or fragments of PT32, it is necessary to have additional guidance and to carry out further experimentation to assess the effect of the variant or fragment of PT32.

(6). Nature of the Invention

The scope of the claims includes many sequence variants, however the specification has not identified the polynucleotides encoding variants or fragments of PT32, nor has demonstrated the effects of the PT32 variants or fragments. Thus, the disclosure is not enabling for reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not demonstrate the claimed variants, and the teaching in the specification is limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effect of the claimed invention.

4. Claims 61 and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 61 and 62 are directed to a polynucleotide comprising a sequence that is at least 75% identical to nucleotides 36 to 933 of SEQ ID NO:4 or to nucleotides 1 to 705 of SEQ ID NO:11. The specification indicates that the present invention is directed to polynucleotides having at 75% or 90% identity, and preferably at least 95% identity to a polynucleotide which encodes PT32, e.g., the polypeptide of SEQ ID NO:5 or 12, which can be encoded by the polynucleotide of SEQ ID NO:4 or 11 (page 22, paragraph [0055]). However, the specification has not identified a specific variant or fragment of SEQ ID NO:4 or 11 exhibiting at least 75% sequence identity to nucleotides 36 to 933 of SEQ ID NO:4 or nucleotides 1 to 705 of SEQ ID NO:11, and encoding a functional polypeptide. There are no examples indicating variants or fragments of SEQ ID NO:4 or 11 exhibiting at least 75% sequence identity to nucleotides 36 to 933 of SEQ ID NO:4 or nucleotides 1 to 705 of SEQ ID NO:11, and encoding a functional polypeptide. Without guidance on structure to function/activity of the polynucleotides, one skilled in the art would not know which region of nucleotides is essential for coding a polypeptide which has function/activity, and how to identify a polynucleotide encoding a functional polypeptide. The lack of a structure to function/activity relationship and the lack of representative species for the polynucleotides comprising a sequence that is at least 75% identical to nucleotides 36 to 933 of SEQ ID NO:4 or nucleotides 1 to 705 of SEQ ID NO:11 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9, 10, 48 and 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 9 and 48 are indefinite because of the use of the term "a conservative variant thereof". The term "a conservative variant thereof" renders the claim indefinite, it is not clear what sequence the variant has, and how different the variant is from the parent sequence.

7. Claim 10 is indefinite because of the use of the term "a degerate variant thereof". The term "a degerate variant thereof" renders the claim indefinite, it is not clear what sequence the variant has, and how different the variant is from the parent sequence.

8. Claim 67 is indefinite because of the use of the term "adapter protein". The term "adapter protein" renders the claim indefinite, it is not clear what the "adapter protein" is.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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January 5, 2004

ROBERT A. WAX
PRIMARY EXAMINER